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Mr. William Hubbard
Document Management Branch
HFA #305, FDA, 5630
Fisher's Lane, Rm 1061
Rockville, MD 20852

Re: Document No. 98p-0504

Dear Sir,

As founder of Brady's Oyster Co. (in business for over 30 years) I would like to comment on the proposed rule change for *Vibrio vulnificus* (Vv) control. I would like to express the unfairness of actions that may be placed on Washington oyster growers. Controls on Vv are necessary to protect public health and welfare, this is understood, but the heavy handed one size fits all regulations will eliminate safe shellfish with the bad. In the eyes of local shellfish growers this is unacceptable.

It is important to control only those areas that contribute to the problem and not do collateral damage to harvest areas that have provided a continuing safe supply of oyster products to distant markets throughout the nation. The making of this problem does not rest with Washington state growers but can be attributed to warmer water areas of the Gulf and South eastern seaboard. This is where the controls need to be placed.

The most judicious and amenable way to resolve the Vv problem is to let the Interstate Shellfish Sanitation Commission (ISSC) deal with the problem. They have the frame work to resolve complicated and contentious issues and have been effective in the past. Stakeholders make better decisions and their decisions will be much better received than rules applied from a federal agency without localized input.

Thank you for the opportunity to comment and please find inclosed a newspaper article printed in the Chinook Observer dated April 14th, 1999. This article expresses our local concern.

Sincerely,
Brady Engvall

Date: 4-20-99



98P-0504

C204

No more live oysters on the half shell?

■ Federal rule aimed at Gulf and Atlantic coasts could doom many NW growers

By ED HUNT
Observer science writer

BAY CENTER—The U.S. Food and Drug Administration is considering action that could take raw oysters off the menu and push as many as 75 percent of shellfish growers out of business across the nation, according to the Pacific Coast Oyster Growers Association.

The Center for Science in the Public Interest—a national advocacy group based in Washington,

D.C.—is asking the FDA for stricter controls on the sale of raw oysters and other shellfish.

'This is quite serious. It could wipe a lot of people out.'

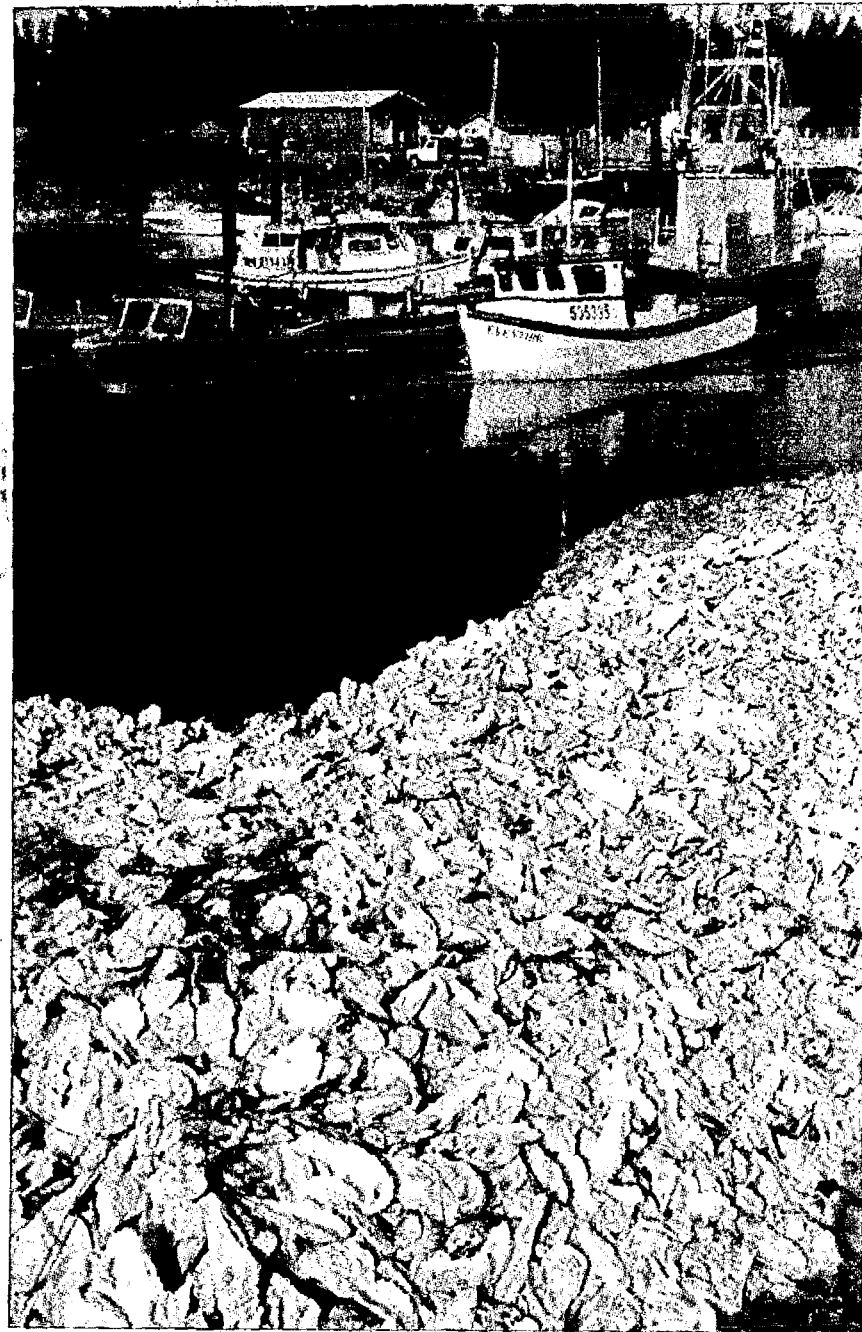
Dick Wilson
Owner of Bay Center Mariculture

While the action is directed against Gulf and Atlantic coast growers, it may have dire consequences for Pacific Coast growers who already operate under shellfish safety measures at the state level

but who face less danger from shellfish safety problems than growers in warmer waters.

"We really don't see it as a West Coast problem," said Darren Mitchell, staff attorney for CSPI. "It's really a Gulf Coast problem. The performance standard we are calling for is for all waters in which deaths or illness have been attributed to *Vibrio vulnificus*."

The group filed a petition in June 1998 asking the FDA to force Gulf Coast growers to "eliminate certain



STAN THOMPSON photo

The oyster business is a key part of the economy in Nahcotta, South Bend, Bay Center and Oysterville, but a proposed federal rule places those jobs at risk. Growers rely on lucrative sales of oysters for consumption live on the half shell. The new rule would require oysters to go through an expensive process before sale that kills bacteria and the oyster itself. Though the oysters can still be eaten in the shell, they must be eaten within hours, or else they become rubbery.

dangerous bacteria from its oysters." According to the group, the petition asks FDA to require that shellfish sold for raw consumption be free of the

bacteria, called *Vibrio vulnificus*. Virtually all of the 177 reported cases

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since 1989 have been linked to the warm waters of the Gulf of Mexico or Florida's Atlantic Coast.

The potential impact to West Coast growers stems from the different standards and different water conditions faced by shellfish growers on the Pacific and Atlantic coasts and the Gulf of Mexico, explained Kathleen Sayce, bank scientist with Shorebank Pacific in Ilwaco. Sayce said the type of bacteria the advocacy group is targeting is naturally occurring in all coastal waters of the United States. It doesn't become harmful until water temperature exceeds 20 or 21 degrees Celsius, or about 68 degrees F.

Pacific coast waters—especially those in Willapa Bay—rarely get that warm, although they did reach these temperatures during the recent extreme El Niño event, which suppressed the upwelling of cool waters off the Northwest coast and attracted tropical fish to Washington's marine waters. On the East Coast, and particularly the Gulf Coast of the U.S., the water often exceeds these temperatures thanks to the warm water of the Gulf Stream.

Sayce says that state regulations for West Coast and East Coast growers also differ significantly. Pacific Coast growers have limits on the amount of bacteria that can be present in the water before an area is closed to harvest; on the East Coast, growers have resisted such standards, and handling practices there often allow growers to circumvent protections, Sayce said.

"The rules for shellfish handling in the West are much more stringent than they are in the East, and 30 to 40 people get sick and die back there every year," Sayce said. "That's no overstatement—eating shellfish in those states is much riskier. I don't know how they've gotten away with it. It's amazing

asked that the matter be referred to the Interstate Shellfish Sanitation Conference, which is made up of state and federal health regulators and member of the industry. The ISSC debates public health issues in detail and tries to bring in the best available science. It also tries to make sure that whatever regulatory changes are being proposed can actually be implemented by the growers, Downey said.

"There will never be enough enforcement officers out to enforce these laws, so we need to self regulate," Downey said. "So we've asked that FDA to refer it to the ISSC and to give funding to do the science we need to come up with the best regulation possible—not just non-detectable. If the level is set at non-detectable, that's going to mean no more raw oysters."

Pacific oyster growers are asking that the tighter controls they put in after 1997 continue to be used for two more years while research is stepped up and self regulation is tightened. Consumer education and pulling the product during warm weather events is important as well, Downey said.

However, it's also important not to change procedures—possibly impacting the whole West Coast industry—based on what could be a n o m a l o u s weather event, Downey added.

Mitchell said his health advocacy group is still not happy with the controls in place because they "require someone to get sick before shutting down shellfish harvesting"

method called AmeriPure. Irradiation is before the FDA and is likely to be approved and pressurization techniques are under development, Mitchell said.

The problem, says Downey, is that the growers she represents are mostly small "mom and pop" type operations that would never be able to afford to pay \$250,000 for the pasteurization machine. Additionally, the market wouldn't support simply passing the cost on to consumers as Mitchell's organization suggests.

NW industry at risk of destruction

Downey says the pasteurization process kills the oyster and a rubber band is needed to keep the oyster shell shut. If eaten a few hours after cooking it tastes like a raw oyster, she says, "but if you wait too long, it tastes like rubber bands."

"A majority of shellfish growers would be brought to their knees and the market would not be able to bear it," Downey said. "Since AmeriPure has the only approved process, it's a sweet deal for them, but it will wipe out 75 percent of growers across the country. Small mom and pop growers can't do this sort of retrofit."

This has huge economic implications," Downey said requiring that no detectable bacteria be present in oysters could force 75 percent of the nation's growers out of business and would eliminate the sale of raw oysters.

For Pacific Coast growers,

selling raw or live oysters has become a mainstay of their business. Great tasting oysters live and

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Kathleen Sayce
Peninsula biologist

shellfish in those states is much riskier. I don't know how they've gotten away with it. It's amazing that those states haven't stepped in and said 'We've got to do something.'

The strain of bacteria is different as well, Sayce said. While *Vibrio vulnificus* is present in West Coast waters, a different, less harmful type of the bacteria—*Vibrio parahaemolyticus*—is much more common. (See related story.)

Because a number of illnesses were reported in 1997 due to *Vibrio parahaemolyticus*, the petition also calls for FDA to take a closer look at the standards of acceptable concentrations of this bacteria as well, said Robin Downey, executive director for the Pacific Coast Oyster Growers Association.

After the warm waters of an emerging El Niño caused a West Coast outbreak in 1997, Pacific Coast Oyster Growers lowered the threshold for *Vibrio* concentrations and imposed a voluntary shutdown of raw oyster sales when waters became unusually warm again in 1998. Downey said this avoided many illnesses and is proof that the self regulation of West Coast growers works.

Two bacteria lumped together

Downey is worried that the two different strains of *Vibrio* are being lumped together. No deaths or long-term effects have been found from *Vibrio parahaemolyticus* (VP). She's afraid FDA will adopt a requirement for no detectable bacteria. Such a requirement would put an end to raw shellfish sales because there is usually a non-harmful amount of bacteria naturally occurring in the water.

"We're between a rock and hard place in terms of public health," Downey said. "We should consider setting a new standard, but the standard should not be set at zero. The petition says we might as well

set a new standard for VP while we're at it, but they don't suggest what kind of standard should be set."

The Pacific Coast growers have

"require someone to get sick before shutting down shellfish harvesting" because the current threshold is set too high.

However, he agrees with PCOGA that more research needs to be done to set a "safe" level of *Vibrio* and a threshold to trigger a harvest shutdown. Yet, Mitchell says his group does not want to see this process go through the ISSC.

"It's really time for the FDA to step in," Mitchell said. "They really have the authority to come up with performance standards that everyone should meet."

Mitchell said FDA needs to require that growers determine what hazards are applicable to their product and develop and put in place controls for those hazards in their processing.

One way to control those hazards would be simply to delay harvest—or to harvest, but sell only for the cooked market—which is how Pacific Coast growers handled things in 1998, Mitchell admitted.

"There's no doubt that Pacific Coast growers acted responsibly," Mitchell said. "But the response is too late when you wait for human illness to trigger it. It needs to be more pro-active. They need to take that no-harvest step when *Vibrio* are above a truly accurate threshold. The key is where to set that number."

"We agree that more science needs to be done," Mitchell continued. "It's way too high where it is now, and even PCOGA agrees with that." Mitchell says that if FDA puts in place a requirement to reduce pathogens in shellfish, the technology providers will come up with new technology to meet the need for a way to kill the bacteria.

Already there is one method approved by FDA and on the market—a patented heat pasteurization

become a mainstay of their business. Great tasting oysters live and in the shell can fetch a higher price in a business with narrow margins. If the FDA forces them to use a process that kills all bacteria they could lose that market altogether.

"This has become a big part of our business," said Dick Wilson, owner of Bay Center Mariculture. "Last year we shipped 120,000 dozen, this year we'll probably do more. But they want the oyster live and cold in the shell. You can get a cooked oyster anywhere."

In fact, it could impact any shellfish that comes out of U.S. coastal water, Wilson said.

"This is quite serious," Wilson said. "It could wipe a lot of people out. It would really hurt the business and market we've built." Downey argues that there are much greater health risks for the FDA to concern itself with. More people get sick from mayonnaise than from Pacific Coast oysters.

"This thing has been around as long as human history and it's ridiculous to suddenly force people to go with a completely different product," Downey said. "So we're hoping the FDA will look at the true health impact, the anomalous weather and the dearth of science and allow us to put a control plan into effect. If there is enough of a political response urging them to do that, they'll do that right thing. We have reason on our side."

The FDA is currently taking comments on what action it should take. Comments can be sent to William Hubbard, Document Management Branch, HFA-305, FDA, 5630, Fisher's Lane, Rm. 1061, Rockville MD, 20852. Refer to Document No. 98p-0504 by April 21.

Ed Hunt is the editor of the Tidepool.org internet news service.

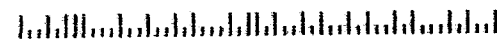
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